UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE PAULSBORO DERAILMENT CASES	:	**MASTER DOCKET NO.: 13-CV-784 (RBK/KMW)**
MARLO JOHNSON,	:	
	:	**CASE NO: 1:13-CV-04569-RBK-KMW**
Plaintiff,	:	
v.	:	
CONSOLIDATED RAIL CORPORATION, *et al.*,	:	
Defendants.	:	

DEFENDANTS CONSOLIDATED RAIL CORPORATION, NORFOLK SOUTHERN RAILWAY COMPANY AND CSX TRANSPORTATION, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF ROBERT LAUMBACH, M.D, M.P.H., C.I.H.

Filed on behalf of Defendants,
Consolidated Rail Corporation,
Norfolk Southern Railway Company
and CSX Transportation, Inc.

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COME NOW Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc. ("Defendants"), by and through their counsel, Burns White LLC, and submit this Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Robert Laumbach, M.D., M.P.H., C.I.H.

I. PRELIMINARY STATEMENT

Plaintiff, Marlo Johnson ("Plaintiff") has retained Robert Laumbach, M.D., M.P.H., C.I.H., to provide expert testimony in support of his toxic-tort claims. Dr. Laumbach's opinions are intended to establish that Plaintiff's brief, acute exposure to vinyl chloride and its

degradation products from a November 30, 2012 train derailment in Paulsboro, New Jersey resulted in an increased risk of cancer and a need for medical monitoring for liver cancer.

As explained below, Dr. Laumbach's expert analysis is littered with methodological shortcomings. With regard to general causation (whether vinyl chloride or its degradation products can cause the alleged injuries), Dr. Laumbach purports to follow the Bradford Hill factors in assessing causation. However, simply citing Bradford Hill is not enough—Dr. Laumbach must actually use this methodology in developing his causation opinion. Closer scrutiny reveals that his opinions fly in the face of the Bradford Hill criteria and have no scientifically-recognized foundation.

Likewise, Dr. Laumbach's medical monitoring opinions are speculative and unreliable. They should be excluded because they are based on flawed and unsupported assumptions regarding the long-term risks of acute vinyl chloride exposure, and because he fails to establish that the monitoring program that he proposes is medically appropriate. Finally, all of the opinions contained in Dr. Laumbach's report, which are based in part on the National Transportation Safety Board "(NTSB") report, are improper and must be excluded.

In the end, Dr. Laumbach's opinions are no more than subjective views without an objective scientific foundation. His opinions are the product of litigation, not reliable application of generally accepted scientific methods and principles. Accordingly, the expert report, opinions and testimony of Dr. Laumbach should be excluded, as they fail to satisfy the *Daubert* standards and Fed. R. Evid. 702. Additionally, the probative value of such opinions is greatly outweighed by the probability that they will lead to unfair prejudice and jury confusion, thereby warranting exclusion under Fed. R. Evid. 403.

II. SUMMARY OF DR. LAUMBACH'S QUALIFICATIONS AND OPINIONS

Dr. Laumbach is a medical doctor who is board certified in family medicine and occupational medicine. *See* May 6, 2015, deposition of Dr. Laumbach at p. 34, attached hereto as Exhibit A. According to his April 4, 2015 expert report, attached hereto as Exhibit B, Dr. Laumbach is a self-proclaimed "expert in occupational and environmental medicine [and] its main academic disciplines of epidemiology and toxicology," Laumbach Rep. at 2. However, Dr. Laumbach does not hold any degrees in either epidemiology or toxicology. Laumbach Dep. at 40-41. Additionally, prior to this case, Dr. Laumbach had never done any research or published any papers related to vinyl chloride. *Id.* at 34-35.

Based on his deposition testimony and his April 11, 2015 expert report, it appears Dr. Laumbach's proposed testimony in this matter will include the following opinions:

- Plaintiff had an uncertain amount of exposure to vinyl chloride and its decay products.
- His exposures leave him with an increased risk of liver cancer and medical monitoring is warranted.

See generally, Laumbach Rep. and Laumbach Dep.

III. ARGUMENT AND CITATION OF AUTHORITIES

A. Standards For Evaluation Of A Motion To Exclude Expert Testimony.

It is well-established that district courts are to conduct a "rigorous" analysis to ensure expert evidence satisfies the *Daubert* requirements and Rule 702 of the Federal Rules of Evidence before admitting expert testimony or opinions into evidence. *See, e.g., Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993). Briefly stated, those requirements are: (1) the witness must qualify as an expert; (2) the testimony or opinions must be reliable; and (3) the expert testimony or opinions must assist the trier of fact and "fit" the facts of the case. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).

With respect to the qualifications prong of the inquiry under *Daubert* and Rule 702, expert testimony should be excluded unless it is shown that the witness possesses sufficient specialized expertise in the field in which he or she is proffered as an expert. *Elcock v. Kmart Corp.*, 233 F.3d 734, 744 (3d Cir. 2000).

The reliability prong mandates "that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert*, 509 U.S. at 590). A court "is not required to simply 'take the expert's word for it.'" *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 563 (W.D. Pa. 2003). As this Court has explained, the Third Circuit has developed an eight-part test for evaluating the reliability or scientific validity of purported expert testimony: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *United States v. Schiff*, 538 F. Supp. 2d 818, 833 (D.N.J. 2008) (quoting *United States v. Mitchell*, 365 F.3d 215, 235 (3d Cir. 2004)).

Finally, the expert testimony has to "fit"—that is, the court must determine that the opinion "is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591. Expert testimony that does not relate to the specific issues before the trier of fact "is not relevant and, ergo, non-helpful." *Id.*

In toxic tort cases such as this, Plaintiff must prove "both general and specific causation about the effects of the toxic substance." *See, e.g., Merrell Dow Pharmaceuticals v. Havner,* 953 S.W.2d 706,714-15 (Tex. 1997); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 593 (D.N.J. 2002), *aff'd*, 68 Fed. Appx. 356 (3d Cir. 2003) (recognizing the need to prove general and specific causation). Accordingly, Plaintiff must establish that: (1) vinyl chloride or its degradation products are capable of causing the injuries alleged; and that (2) vinyl chloride or its degradation products actually caused the specific injuries involved in the case.

In other words, Plaintiff must first show that there is a credible and reliable scientific basis, with scientific degree of certainty, that vinyl chloride or its degradation products, in the amount encountered by Plaintiff, can have the sorts of toxic effects alleged. Then, a showing must be made, by using a differential diagnosis carried out using proper scientific methodology, that the harm Plaintiff suffered was more likely than not caused by the exposure to vinyl chloride or its degradation products. Here, Dr. Laumbach fails on both accounts.

B. All Of The Opinions Contained In Dr. Laumbach's Report, Which Are Based In Part On The NTSB Report, Are Improper And Must Be Excluded.

Dr. Laumbach has improperly relied upon the NTSB Accident Report and Factual Report as the underlying basis for all of his opinions in this case. *See* Laumbach Rep. at 2; Laumbach Dep. at 68-69. 81-82. 49 U.S.C. § 1154(b) states that "[n]o part of a report of the Board, related to an accident or an investigation of an accident, may be admitted into evidence or used in a civil action for damages resulting from a matter mentioned in the report." 49 U.S.C. § 1154(b); *see also* 49 C.F.R. § 835.2 ("no part of a Board accident report may be admitted as evidence or used in any suit or action for damages growing out of any matter mentioned in such reports"). The clear language of 49 U.S.C. § 1154(b) mandates that expert reports based on NTSB reports, which rely on the information and conclusions contained in those reports, may not be introduced

into evidence in a subsequent civil trial. *Louisiana ex rel. Dept. of Transp. & Dev. v. Kition Shipping Co., Ltd.*, 653 F.Supp.2d 633, 647–48 (M.D. La. 2009).

Recently in *Credle v. Smith and Smith, Inc*., 42 F. Supp. 3d 596 (D.N.J. 2013), this Court faced the same issue arising here—permissibility of use by an expert of portions of an NTSB report. In *Credle*, the NTSB issued a Marine Accident Brief relating to the sinking of a scallop boat that sank off the coast of Cape May, New Jersey. The Brief included descriptions of the investigation, history of the vessel, conditions on the day of the sinking, probable cause of the incident, and a safety recommendation based on the results of the report. Plaintiff's expert based a number of his findings of fact and conclusions on information contained in the Marine Accident Brief. The defendants filed a motion *in limine* seeking to preclude the introduction of any evidence that the NTSB issued in its Marine Accident Brief or any of the opinions and conclusion set forth in the Brief. The New Jersey District Court held that, while expert witnesses may in certain circumstances base their opinion on inadmissible evidence under the Federal Rules of Evidence, the clear language of Section 1154(b) mandates that expert reports based on NTSB reports, which rely on the information and conclusions contained in those NTSB reports, may not be introduced into evidence in a subsequent civil trial. Accordingly, the court granted Defendant's motion *in limine*.

Likewise, here, Dr. Laumbach improperly bases his opinions on inadmissible evidence from the NTSB reports. Plaintiff's attempt to sneak this inadmissible evidence into this trial through the report of his expert should not be permitted. As the Ninth Circuit has cautioned regarding inappropriate reliance on expert testimony, "if what an expert has to say is instead tangential to the real issues, the jury may follow the 'expert' down the garden path and thus focus unduly on the expert's issues to the detriment of issues that are in fact controlling." *Rogers*

v. Raymark Industries, Inc., 922 F.2d 1426, 1431 (9th Cir. 1991). Accordingly, all of the opinions contained in his report, which are based in part on the NTSB report, are improper and must be excluded.

C. Dr. Laumbach's Opinions Must Be Excluded Because They Do Not Result From Reliable Principles Or Methodologies.

1. Dr. Laumbach's Passing and Gratuitous Reference to the Bradford Hill Criteria Does Not Resurrect his General Causation Opinion.

The Bradford Hill criteria have been widely recognized by courts throughout the United States for their usefulness in providing a framework for identifying the generally accepted methodology for making determinations of medical causation. *See Federal Judicial Center's Reference Manual on Scientific Evidence, Third*. (2011) at 601-06 (providing descriptions of the Bradford Hill factors)*; see also* Declaration of Michael I. Greenberg, MD, MPH, attached hereto as Exhibit C; Declaration of Douglas L. Weed, M.D., M.P.H., Ph.D., attached hereto as Exhibit D, Exhibit A at 23-26. The Bradford Hill factors include whether: (1) a temporal relationship exists; (2) the association is strong or weak; (3) a dose-response relationship exists; (4) the results have been replicated; (5) the association is biologically plausible; (6) alternative explanations have been adequately considered; (7) the association exhibits specificity; and (8) the findings are consistent with other knowledge. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 *F.* Supp.2d 584, 592 (D.N.J.2002)(citing the Bradford Hill factors). The Bradford Hill criteria are key to determining whether an expert's causation opinion is reliable and based on sound scientific principles, or as here, is fatally flawed.

In his report, Dr. Laumbach states that his "methodology includes assessment of the Bradford-Hill factors as they apply to evaluation of causation." Laumbach Rep. at 1. Likewise, Dr. Laumbach has testified that the factors are applicable to the alleged acute exposures in this

case. Laumbach Dep. at 51. However, despite his supposed endorsement of the Bradford Hill criteria, these same factors are never mentioned, much less described or applied in his report. Weed Declaration, Exhibit B. at 10. It is insufficient to claim to use a methodology without actually showing how that same methodology was applied. *Id.*

Indeed, Dr. Laumbach's theory, or hypothesis, that exposure to vinyl chloride or its decay products in the amount allegedly encountered by Plaintiff can cause cancer fails to satisfy the Bradford Hill criteria.

- *Strength of Association* (the mathematical odds of developing the outcome of interest from being exposed to the proposed agent). In the case of Plaintiff, there is no documented exposure to vinyl chloride or its decay products, thus there is no strength of association. In addition, there is no evidence in the peer review literature that brief environmental exposure to very low levels of vinyl chloride or its decay products are associated with the development of cancer or other choric medical problems. *Id.*
- *Consistency or reproducibility* (do we see the same outcomes in different studies with different populations and designs). There are no reports in the medical literature of similar environmental exposures involving vinyl chloride causing cancer or disease, and thus no consistency of association. *Id.*
- *Biological gradient* (increasing risk or severity of the outcome of interest in association with an increased dose). There is no biological gradient that has been established with regard to the alleged exposure in this case. *Id.*
- *Biologic plausibility* (is there agreement with our current understanding of how cells and organs react and respond). There is no biological plausibility with regard to the development of any disease, including cancer, as a result of any alleged exposures in this

case. *Id.*

- *Specificity of association* (is the association limited to a single cause and effect). There is no single cause and effect in this case and thus the element of "specificity of association" is not met. *Id.*
- *Coherence* (are the results in agreement with our current understanding of the distributions of causes and outcomes in humans). There is no coherence with regard to the development of any disease including cancer as a result of any environmental vinyl chloride exposure. *Id.*
- *Experimental or intervention effect* (do the observed effects decrease or stop when the exposure is removed). Plaintiff is not complaining of any specific medical effects related to vinyl chloride exposure. *Id.*
- *Analogy* (are there other similar chemicals that are known to act in the same fashion). There are no reports in the peer-reviewed medical literature of the development of disease including cancer resulting from brief environmental exposures to vinyl chloride. Thus, there is no consistency of association with regard to this matter. *Id.*

Undoubtedly, Dr. Laumbach's methodology in this case is lacking. He did not undertake any formal process to weigh the studies he reviewed, nor has he weighed one more than another. He does not include all of the available vinyl chloride literature in his analysis, and his basis for selective exclusion demonstrates bias. He has relied upon animal toxicology studies without providing a basis for this Court to test whether such extrapolation is appropriate. Instead, in what amounts to an effort to cover up a complete lack of accepted methodology in formulating his general causation "opinion," Dr. Laumbach invokes the Bradford Hill Criteria in name only. His result-oriented conclusions are too great a leap from the scientific literature and accepted

methodology to be admissible. *See In re Breast Implant Litig*., 11 F. Supp. 2d 1217, 1234 n.5 (D. Colo. 1998) (while all factors of the Bradford Hill criteria need not be present to demonstrate causality, failure to address, much less follow, the Bradford Hill criteria renders an expert's methodology unreliable).

It follows that Dr. Laumbach's opinions on general causation regarding the health effects of vinyl chloride exposure lack an objective scientific foundation. As such, he offers nothing more than subjective opinions lacking in reliability.

2. Dr. Laumbach Has Not Properly Analyzed Plaintiff's Level Of Exposure, Which Renders All Of His Causation Opinions Unreliable, Irrelevant And Inadmissible.

Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden in a toxic tort case. *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105 (8th Cir. 1996). "[A] plaintiff must prove level of exposure using techniques subject to objective, independent validation in the scientific community. At a minimum, the expert testimony should include a description of the method used to arrive at the level of exposure and scientific data supporting the determination." *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998) (internal citations omitted).

Here, Dr. Laumbach's so-called methodology concerning the Plaintiff's alleged exposure levels amounts to mere guesswork. Dr. Laumbach is admittedly not able to quantify any alleged dose of vinyl chloride that Plaintiff may have been exposed to following the derailment. Laumbach Rep. at 20 (Plaintiff was exposed to an unknown amount of vinyl chloride and its atmosphere degradation products"). Instead, Dr. Laumbach works backwards, opining that if a number of people smelled and odor and experienced certain symptoms, then he must have had vinyl chloride exposures of a certain level.

Q: . . . So, if someone tells you that -- in the course of your examination, that they could smell an odor that you determine is consistent with vinyl chloride, does that give you any indication of the level to which that person was exposed?

A: I think, in addition to other facts, such as symptoms that the person may have.

Laumbach Dep. at 70.

This backwards reasoning is a fatal flaw in his methodology. By reversing the process (Plaintiff has symptoms and smelled and odor, therefore, the dose is sufficient), Dr. Laumbach has turned the science of toxicology on its head. Without first determining the Plaintiff's dose, he has improperly "ruled in" vinyl chloride as a cause of the alleged injuries.

Further, to the extent that Dr. Laumbach is opining that smelling an odor on the day of the Paulsboro train derailment is equivalent to an exposure of at least 3,000 ppm, such an opinion is speculative and lacks scientific reliability. *See* Weed Declaration, Exhibit A at 27-33. Odor threshold is not a valid and reliable technique for determining whether or not an individual has been exposed to vinyl chloride, the intensity of that presumed exposure, or any putative health effect of that exposure. *Id.* Furthermore, even if it is assumed that an individual was exposed to vinyl chloride and smelled an odor, this same technique is an unreliable estimate of the amount of vinyl chloride to which that individual may have been exposed. *Id.*

Likewise, Dr. Laumbach is wholly unable to establish the dose of any particular constituent of the degradation products of vinyl chloride. Laumbach Dep. at 257. By his own admission, Plaintiff's modeling expert does not, and cannot provide any estimates of the constituents, only the levels of the total breakdown. Whether any hydrochloric acid, or any other decay products—at any level—were present after the Paulsboro derailment is unclear. Weed Declaration, Exhibit B at 8. There is no record, and there was no monitoring done of any decay products. *Id.* Without a reference to dose, Dr. Laumbach is engaging in nothing more than

speculation regarding the alleged effects of any decomposition products. *See Castellow v. Chevron USA*, 97 F. Supp. 2d 780 (S.D. Tex. 2000)(the requirement of dose is highlighted by the Bradford-Hill criteria). Accordingly, any opinions that Dr. Laumbach has related to atmospheric decay products must necessarily be excluded.

3. Dr. Laumbach's Opinions Are Premised Upon Inadequate Data and Faulty Assumptions Contrary To The Circumstances Surrounding the Derailment.

As part of its role as gatekeeper, the district court must ensure that the underlying facts and/or data upon which a proffered expert's opinion are based are reliable in and of themselves. If an expert's opinion is based on unreliable facts, the opinion must be excluded. *See In re TMI Litig.*, 193 F.3d 613, 697 (3d Cir. 1999).

Here, Dr. Laumbach has selectively cherry picked the exposure data that best suits his opinions. For example, he did not consider the Paulsboro Refinery Data, although he admits at his deposition that it was taken in closest proximity to the release, and would therefore be useful. Laumbach Dep. at 86-87. His report also mentions that OxyVinyls did air monitoring on the morning of the derailment, but he likewise failed to review or otherwise consider those monitoring results. *Id.* at 90-92. Similarly, he notes that CTEH did monitoring and he reviewed those results, but again, he failed to include them in his report. *Id.* at 95. Dr. Laumbach also failed to utilize the results of the TAGA bus monitoring. *Id.* at 109.

Instead of relying on actual monitoring data, Dr. Laumbach bases his opinions primarily on the Plaintiff's modeling expert, Panos Georgeopoulos. However, as further articulated in Railroad Defendants' motion to exclude his report and testimony, the results presented by Dr. Georgeopoulos are not an accurate representation of the transport and dispersion of vinyl chloride around Paulsboro. *Id.* To the extent Dr. Georgeopoulos is precluded from giving expert

testimony due to his own methodological problems, Dr. Laumbach's opinion is likewise subject to exclusion.

Dr. Laumbach also inappropriately relies on the ALOHA model[1] to establish the level of vinyl chloride exposure to Plaintiff. *See* Declaration of Lloyd L. Schulman, Ph.D., attached hereto as Exhibit E. This ALOHA run cited predicts that the vinyl chloride concentrations could have exceeded 4,800 ppm as far out as 1383 yards in the direction of the wind.[2] *Id.* However, the ALOHA model has several reliability limitations. Specifically, ALOHA was developed as a tool to aid in real-time, emergency response to chemical spills. *See* Shulman Declaration. According to the ALOHA User's Manual, "[i]ts computations represent a compromise between accuracy and speed; ALOHA has been designed to produce good results quickly enough to be of use to responders." *Id.* "Wherever uncertainty is unavoidable, ALOHA will err in favor of overestimating rather than underestimating threat distances. *Id.* In some cases, *ALOHA will significantly overestimate threat zones*." *Id*. Even Plaintiffs' own modeling expert concedes that ALOHA models are not reliable predictors of concentration levels. *See* April 30, 2105 Deposition of Panos Georgopoulos at 178-181, attached hereto as Exhibit F.

Accordingly, the ALOHA model was not an actual reflection of the alleged exposures, but instead, a "worst case" modeling that did not incorporate the actual conditions, in particular the

[1] Areal Locations of Hazardous Atmospheres (ALOHA) is a free web-based software program for chemical release modeling. It is utilized by emergency responders to make reasonable evacuation decisions and was referenced in the NTSB hearings.

[2] Dr. Laumbach also fails to cite to the National Oceanic and Atmospheric Administration (NOAA) plume modeling conducted by the United States Coast Guard, which predicted that vinyl chloride concentrations would only have reached 250 ppm as far out as 0.8 miles. Although he acknowledges in his deposition that there is a significant difference between the two results, he only included in his report the model that had virtually double the area of exposure. Laumbach Dep. at 233-234. Obviously, his decision to base his opinion on the model with the greatest level of exposure with no scientific basis to do so is troublesome.

wind direction, at the time of the derailment. In fact, even when accurate input information is available, ALOHA's results can be unreliable, and under some conditions, there are some effects that ALOHA does not model at all. *See* Schulman Declaration. According to the User's Manual, ALOHA's results can be unreliable when the following conditions exist: very low wind speeds; very stable atmospheric conditions; wind shifts and terrain steering effects; or concentration patchiness, particularly near the release source. *Id.* All of these conditions existed during the first hour after the vinyl chloride release. *Id.*

There were additional problems with the ALOHA model: (1) this run did not correctly account for the amount and duration of the release; (2) the dispersion characteristics did not reflect the actual release because it used the computer clock time of 10:50 a.m. EST, instead of the actual derailment time of 7:00 a.m. EST; (3) no terrain is allowed in the run, so the model fails to account for the fact that vinyl chloride was trapped in the creek channel; and (4) the wind direction was modeled as north-northeast at two (2) knots, which was not the wind direction at the time of the accident. *Id.* Accordingly, the ALOHA results do not accurately portray the dispersion of vinyl chloride at the time of the derailment, and Dr. Laumbach should not be permitted blindly rely on the model to reach his conclusions.

Undoubtedly, Dr. Laumbach's opinions are based on unreliable facts. Moreover, because the models do not reflect the actual conditions at the time of the derailment, his opinions do not "fit" the facts of this case, thereby warranting exclusion.

4. Dr. Laumbach Cannot Establish General Causation—That Vinyl Chloride Causes The Health Effects From Which Plaintiff Allegedly Suffers Or May Develop in the Future.

A central tenet of toxicology is that "the dose makes the poison." Bernard D. Goldstein and Mary Sue Henifin, *Reference Guide on Toxicology* in *Federal Judicial Center Reference*

Manual on Scientific Evidence (hereafter, "*Reference Guide on Toxicology*"), at 636 (3d ed. 2011). This principle "implies that all chemical agents are intrinsically hazardous—whether they cause harm is only a question of dose." *Id*. Accordingly, an expert witness cannot establish that a plaintiff's exposure to a certain chemical was capable of causing his or her illness merely by citing studies in which far greater doses were shown to produce that illness. Instead, the expert must also be able to explain why extrapolation from higher doses to lower doses is scientifically valid under the circumstances presented. *Id*. at 646; *see also Baker v. Chevron*, 680 F. Supp. 2d 865 (S.D. Ohio 2010) (excluding expert's causation opinion based on multiple epidemiological studies in which the levels or durations of exposure were not comparable to those allegedly experienced by the plaintiffs).

Moreover, different species may respond differently to a given chemical. *See* Reference Guide on Toxicology at 646. For an expert to be able to rely on animal studies as support for a causation opinion in a toxic-tort case, he or she must also be able to explain why extrapolation from animal data to humans is scientifically valid. *Id*. "The expert should review similarities and differences between the animal species in which the compound has been tested and humans. This analysis should form the basis of the expert's opinion regarding whether extrapolation from animals to humans is warranted." *Id*. at 661. "The failure to review similarities and differences in performing cross-species extrapolation has led to the exclusion of opinions based on animal data." *Id*. at 661 n.77.

Dr. Laumbach's report in this case "cherry-picks" studies that conform to his pre-conceived opinions on the putative health effects of vinyl chloride, rather than providing an objective description and evaluation of the available evidence. Weed Declaration, Exhibit B. at 8. This shortcoming is fatal to the admissibility of Dr. Laumbach's expert testimony and

opinions here. Rule 702 jurisprudence recognizes that unsupported assumptions, unexplained or unjustified extrapolations, and leaps of faith or lapses in logic are badges of unreliable, speculative, and unscientific conclusions. Under these circumstances, the reliance on the referenced studies violates both the reliability requirements and the "fit" requirements of Rule 702.

a. Vinyl Chloride Carcinogenesis

Hepatocellular carcinoma and hepatic angiosarcoma, rare types of liver cancer, are linked with chronic exposure to vinyl chloride, such as in the occupational setting. *See* Declaration of Lee Hartner, M.D., attached here to as Exhibit G; *see also* Weed Declaration, Exhibit A at 35 ("A causal relationship between vinyl chloride and angiosarcoma of the liver in human populations has only ever been observed in occupational groups involving in the manufacture and production of vinyl chloride."); *id.* ("Extremely high levels of cumulative exposure to vinyl chloride—in terms of ppm-years of cumulative exposure—are needed to cause HHC [hepatic cell carcinoma]"). In the context of acute exposure to vinyl chloride, however, there is no evidence-based study that definitely demonstrates the ability of brief vinyl exposure to increase the risk of hepatocellular carcinoma and hepatic angiosarcoma. *See* Declaration of Michael Morse, M.D., attached hereto as Exhibit H. In fact, in a presentation that he made to first responders before he was retained as an expert in this case, Dr. Laumbach expressly acknowledged that there is "no evidence from epidemiological studies of occupational VC exposure that short-term exposure results in increased cancer prevalence." *See* Laumbach Dep. at 171; *id.* Exhibit 18.

Despite this admission, Dr. Laumbach makes no attempt to address the critical distinction between acute and chronic exposure. Instead, he relies on studies of chronic, occupational exposure to opine that Plaintiff has an increased risk of contracting rare liver cancers based on

his alleged acute exposure. He relies, for example, on Mundt, *et al.* (2000) and Ward (2001), which he describes as "multicenter cohort studies, in North America and Europe, [that] demonstrate[] very large excesses of angiosarcoma of the liver in workers with occupational exposure to vinyl chloride." Laumbach Rep. at 7. Both reports, as Dr. Laumbach's own description makes clear, focus on workers chronically exposed to vinyl chloride. "Neither report supports the carcinogenicity of brief exposures to vinyl chloride" and, accordingly, the reports cannot be used to assess the impact of a brief exposure on the risk of liver cancer. *See* Hartner Declaration.

In the absence of any relevant scientific studies, Dr. Laumbach turns to the guidelines established by the National Advisory Committee for the Development of Acute Exposure Guideline Levels ("AEGL") to opine that acute exposures to vinyl chloride will increase the risk of cancer by 10^{-4}. *See* Laumbach Rep. at 14-15. The AEGL guidelines for acute exposures are not based on any actual acute exposure data in humans (as noted above—there are no such studies) and represent the Committee's approximation of potential acute exposure risks. *See id.* at 15 (describing the manner in which acute exposure risks were extrapolated from chronic exposure studies and a five-week exposure study involving animals). As Dr. Laumbach states, the AEGLs are "guidelines" developed to help authorities deal with emergency responses involving chemical spills. *Id.* at 13. However, such approximations are insufficient to sustain Dr. Laumbach's opinions here. As a matter of law, agency benchmarks cannot be used as a basis for liability in a civil action. *See, e.g., O'Neal v. Dep't of the Army*, 852 F. Supp. 327, 333 (M.D. Pa. 1994) ("While appropriate for regulatory purposes in which the goal is to be particularly cautious, [EPA's] upper-bound estimates overstate the *actual* risk and, so, are inappropriate for use in determining whether medical monitoring should be instituted."); *Nat'l Bank of Commerce*

v. Associated Milk Producers, Inc., 22 F. Supp. 2d 942, 961 (E.D. Ark. 1998) ("regulatory agencies employ a different perspective in setting 'action levels' than do courts in imposing tort liability. Establishing that the risk of causation 'is not zero' falls woefully short of the degree of proof required by *Daubert* and its progeny"), *aff'd*, 191 F.3d 858 (8th Cir. 1995).

Dr. Laumbach also relies on Hehir (1981), a study involving rats and mice, which he claims "provides evidence to support the plausibility of cancer induction by a single large dose of vinyl chloride." Laumbach Rep. at 15. The conditions of that study, however, do not in any way simulate the situation that occurred in Paulsboro on the day of the derailment. Greenberg Declaration. The study, moreover, reports that when rats (as opposed to mice) were similarly exposed, they showed no tumorgenic effects.[3] Dr. Laumbach makes no attempt to explain why the data relating to the exposed mice (but apparently not the exposed rats) is indicative of cancer risks in humans.

D. Dr. Laumbach's Opinions Regarding Medical Monitoring Should Be Excluded As Speculative And Unreliable.

Dr. Laumbach admits that "[t]here are no standard or routine screening tests for early detection of liver cancer. Laumbach Rep. App'x A. Dr. Laumbach also admits that he does not know the amount of vinyl chloride to which Plaintiff was exposed. *See* Laumbach Rep. at 20 (opining that Plaintiff "had an uncertain amount of exposure to vinyl chloride and its decay products"). Nonetheless, he opines that Plaintiff should have (1) annual evaluations by a physician to assess whether his lifestyle choices he may make in the future, coupled with his vinyl chloride exposure, make screening for liver cancer medically advisable, and (2) annual "lifestyle counselling" to mitigate various unrelated risk factors for liver cancer, including

[3] It is also worth noting that, as Dr. Laumbach's own description of the study makes clear, the study found an increase of pulmonary adenomas with progression to carcinoma, ***not*** an increase in liver cancer (the only type of cancer for which Dr. Laumbach opines Plaintiff should be monitored).

hepatitis B or C infections, cirrhosis, diabetes, excessive alcohol consumption, etc. Laumbach Rep. App'x A. Dr. Laumbach's opinions should be excluded because they are based on the flawed and unsupported assumption that acute exposure to vinyl chloride significantly increases the risk of liver cancer and because he fails to establish that the proposed medical monitoring program is medically appropriate.

1. Dr. Laumbach's Medical Monitoring Opinions Are Based On The Flawed And Unsupported Assumption Regarding The Risk Of Liver Cancer Due To Acute Vinyl Chloride Exposure.

As discussed *supra* Section III.C.4.a, and as Dr. Laumbach himself earlier admitted, there is no causal relationship between acute exposure to vinyl chloride and liver cancer. For this reason alone, Dr. Laumbach's opinion that Plaintiff needs to be medically monitored for liver cancer is fundamentally unreliable. *See* Declaration of Michael Morse, M.D. ("Short term exposure to vinyl chloride would not increase the risk of angiosarcoma of the liver and lifetime screening/medical monitoring with respect to vinyl chloride exposure would not be necessary."). Dr. Laumbach's opinion that Plaintiff is at risk for liver cancer based on Plaintiff's brief, acute exposure to vinyl chloride is nothing more than "unsupported speculation." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742.

2. Dr. Laumbach Fails To Establish That The Proposed Monitoring Is Medically Necessary.

Dr. Laumbach's medical monitoring opinions are also subject to exclusion for the independent reason that he provides no basis as to why the specific medical monitoring that he recommends is medically necessary. "In order for Plaintiff's monitoring to be medically necessary, there needs to be an established causal link between his exposure and an increased risk of hepatic angiosarcoma, evidence that the proposed monitoring scheme can result in early detection and that early detection of hepatic angiosarcoma can result in improvement in his

treatment outcome." Hartner Declaration; *see also Rowe v. E.I DuPont De Nemours & Co.*, No. 06-1810, 2009 U.S. Dist. LEXIS 67389, at *32 (D.N.J. July 29, 2009) (holding that medical monitoring must be reasonable, necessary, and different than any other the plaintiff would otherwise undergo). Because none of those criterion is met here, Hartner Declaration, Dr. Laumbach's opinions are fundamentally unreliable.

Notably, as of the date of his report, Dr. Laumbach does not opine that liver cancer screening through liver ultrasounds, CT scans, and blood tests for tumor markers is medically necessary due to Plaintiff's exposure to vinyl chloride. Laumbach Rep. at 20. Instead, Dr. Laumbach opines that Plaintiff may engage in behavior at some point in the future that, coupled with his exposure to vinyl chloride, may have "synergistic effects on risk of cancer." *Id.* at App'x A. Dr. Laumbach's opinion that any screening may be warranted at some distant point in the future is thus pure speculation.

Dr. Laumbach also fails to cite any evidence whatsoever in support of his opinion that annual "lifestyle counselling" will reduce Plaintiff's risk of developing hepatocellular carcinoma or hepatic angiosarcoma. Indeed, there is "no evidence that any intervention in lifestyle can serve to reduce his risk of developing these diseases." Hartner Declaration.

Absent peer-reviewed studies showing that the monitoring recommended by Dr. Laumbach is beneficial, his opinion does not withstand the *Daubert* test. *See In Re Ingram Barge Co.*, 187 F.R.D. 262, 266 (M.D. La. 1999) (rejecting expert testimony on medical monitoring under *Daubert* because the expert "could point to no studies or peer-reviewed literature which suggested that the testing and monitoring he recommends should be performed"). There is simply "no evidence that the proposed medical monitoring would result in any meaningful improvement in health outcomes with regard to hepatic angiosarcoma." Hartner Declaration. So,

in the end, all Plaintiff offers to support his medical monitoring claims is Dr. Laumbach's "say so." This is wholly insufficient. *See Saldo*, 244 F. Supp. at 563 (holding that a court "is not required simply to 'take the expert's word for it'"); *In re Barge Co.*, 187 F.R.D. at 266 (recognizing that data is required to support the proposed medical monitoring program).

E. The Probative Value Of Dr. Laumbach's Opinions Is Outweighed By The Danger Of Unfair Prejudice, Confusion Of The Issues, And Misleading The Jury.

In addition to meeting the reliability requirement of Rule 702 and *Daubert*, an expert's proffered testimony must also satisfy Rule 403. Even assuming that Dr. Laumbach's opinions are reliable under *Daubert* and Fed. R. Evid. 702, which they are not, his testimony should also be excluded under Fed. R. Evid. 403.

Rule 403 states that evidence, although relevant, may still be excluded from trial, if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury. In this case, the probative value of Dr. Laumbach's opinions is clearly outweighed by these concerns. "The role [of gatekeeper] is especially sensitive in cases 'where the plaintiff claims that exposure to a toxic substance caused his injury, [because a] jury may blindly accept an expert's opinion that conforms with their underlying fears of toxic substances without carefully understanding or examining the basis of that opinion."' *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995).

Plaintiff will likely argue that the assessment of Dr. Laumbach's opinion on this case is a question for the jury. However, the mere fact that Dr. Laumbach has good academic credentials could unfairly influence a jury and distract them from examining whether an adequate scientific basis exists to support his conclusions. The admission of his testimony merely serves to echo Plaintiff's opinion that his alleged exposures following the derailment caused his injuries. As it is of very limited probative value, there is a substantial danger that its admission will result in

unfair prejudice to the Defendant. For this additional reason, Dr. Laumbach's testimony should be excluded.

IV. CONCLUSION

For the foregoing reasons, Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc., respectfully request that this Honorable Court exclude the proffered expert testimony of Robert Laumbach, M.D. Defendants also request that the Court convene a *Daubert* evidentiary hearing on this Motion.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of June, 2015, a copy of the within Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Robert Laumbach, M.D. was served on all counsel of record via efile.

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